

Serial No. 10/748,003  
Response to Office Action

### **Remarks**

Claims 1-11 are pending. Applicants have amended claim 1. Applicants address each of the rejections imposed in the Office Action of June 15, 2006.

#### **Claim Rejections - 35 USC 112**

The Examiner has rejected the claims under 35 USC 112, first paragraph for lack of enablement insofar as sulindac and IL-12 act synergistically. Applicants have amended the claims to recite that the effects of the combination of sulindac and IL-12 is greater than the effect of either one alone for inhibition of growth of tumors. Therefore, this rejection is now rendered moot.

#### **Claim Rejections - 35 USC §103**

Claims 1-11 over Mathiowitz et al. (US 2001/0043914, 2001) or Giardiello et al., 1996 in view of Mathiowitz et al. (U.S. Patent No. 6,235,313, 2001)

Applicants request the Examiner to reconsider the rejection for the following reasons. As noted by the Examiner, neither of the cited references of Mathiowitz ('914) or Giardiello teach or even suggest the administration of the combination of IL-12 and sulindac. Applicants disagree with the Examiner that it would have been obvious for one skilled in the art to combine the two agents. Applicants respectfully point out that sulindac is an anti-inflammatory agent while IL-12 is a pro-inflammatory agent. Therefore, it would not occur to one skilled in the art to administer the two agents together. On the contrary, one skilled in the art would not consider administering the combination because of their counter actions. In support of this contention, Applicants provide a Rule 1.132 Declaration by an expert in the field, Dr. Richard Bankert (Professor of Microbiology at the State University of New York at Buffalo, and the President and a Director of Therapyx Inc., the assignee of the present invention). It is clear from Dr. Bankert's declaration that one skilled in the art would not consider such a therapeutic approach. Similarly, one skilled in the art would not consider combining the two agents for oral administration. Therefore, Applicants respectfully assert that the current claims cannot be deemed as being obvious over the cited references.

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**Conclusion**


Based on the above arguments and amendments, Applicants respectfully submit that none of the cited references, either alone or in combination render the present claims obvious.

Applicants assert claim 1, is allowable, and therefore, dependent claims 2-11 are also allowable.

Therefore, Applicants respectfully request the Examiner to allow these claims.

This response is being filed with a request for two month extension. A check for \$395.00 for the RCE and \$225.00 for the two month extension is enclosed. Any additional fee due may be charged to Deposit Account No. 08-2442.

Respectfully submitted,  
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